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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,982	02/02/2006	Ruggero Fariello	373987-011US (102895)	6583

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DECHERT LLP
P.O. BOX 390460
MOUNTAIN VIEW, CA 94039-0460

EXAMINER	
JAVANMARD, SAHAR	

ART UNIT	PAPER NUMBER
1627	

NOTIFICATION DATE	DELIVERY MODE
10/08/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

napatentdept@dechert.com

Office Action Summary	Application No.	Applicant(s)	
	10/559,982	FARIELLO ET AL.	
	Examiner	Art Unit	
	SAHAR JAVANMARD	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *57-68* is/are pending in the application.

4a) Of the above claim(s) *68* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *57-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/15/10*.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application

6)☐ Other: _____.

DETAILED ACTION

Status of the Application

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 15, 2010 has been entered.

Claim(s) 57-68 are pending. Claim(s) 1-56 are cancelled. Claim(s) 68 is withdrawn from further examination as it is drawn to a non-elected invention. Claim(s) 57-67 are examined herein.

Response to Arguments

Applicant arguments with respect to the 103(a) rejection of claims 57-64 and 67 as being unpatentable over Dostert (US Patent No. 5,236,957) of record and Chiesi (US Patent No. 5,017,607) have been fully considered but are not persuasive.

Applicant arguments with respect to the 103(a) rejection of claims 65 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dostert (US Patent No. 5,236,957) and Chiesi (US Patent No. 5,017,607) as applied to claims 57-64 and 67 above in further view of Chenard (US Patent No. 6,258,827 B1) have been fully considered but are not persuasive.

Applicant argues:

> Chiesi explicitly teaches that the addition of an MAO-B inhibitor to therapy with levodopa methyl ester "allow[s] a remarkable reduction in the dose of LDME necessary to control the disease, consequently decreasing side effects ...." Chiesi, col. 3, lines 9 - 16. The reference is thus fairly read as teaching away from combination therapies in which L-dopa (or prodrug thereof) is administered "in an amount that alone has therapeutic effect," as required by applicants' claims.

This argument is not found persuasive. First, because based on the language of the instant claims, the amount of L-DOPA administered alone in a therapeutic amount is variable and based on the various subjects. Moreover, Chiesi, goes on to teach that "to allow the application of the therapeutic and posological scheme more suited to a particular pathological condition, LDME and the above mentioned active principles may be administered separately. Alternatively, the patient may be administered with therapeutic compositions containing active principles both LDME and a peripheral decarboxylase inhibitor and/or a MAO-B inhibitor or optionally with both of them" (column 3, lines 19-27). Thus, there is no indication that the dosage of LDME alone would not be therapeutically effective.

Furthermore, Applicant cites Stocchi and Meshran (the work of two of the instant authors) as evidence that based on the results of the studies, the combination of safinamide with add-on dosages of L-DOPA were unexpected and therefore render the instant invention novel. This argument is not persuasive as the data presented is after the time of filing.

Based on the reasons of record, the instant rejections are hereby maintained and restated in the Final Office action below for Applicant's convenience.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 57-64 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dostert (US Patent No. 5,236,957) of record and Chiesi (US Patent No. 5,017,607).

Dostert teaches N-phenylalkyl substituted α-amino carboxamide derivatives of formula I as therapeutic agents for the treatment of Parkinson's disease (column 1, line

32-column 2, line 7). Specifically, Dostert teaches (S)-2-[4-(3-fluorobenzyloxy)benzyl]aminopropionamide (column 15, lines 3-4) (a.k.a safinamide).

Dostert additionally teaches pharmaceutically acceptable salts thereof of including among others, methanesulfonic acid (column 2, 28).

Dostert teaches that the compounds may be administered orally at doses ranging from about 50 to about 1500 mg/day (column 12, lines 7-10).

Dostert does not teach the coadministration of L-Dopa which is administered in an amount that alone has therapeutic effect.

Chiesi teaches a method of treating Parkinson's disease containing as the active principle levodopa methyl ester optionally combined with other active principles selected from dopaminergic, anticholinergic, antidepressive drugs, carboxylase and monoaminoxidase inhibitors. In order to improve the therapeutic action, LDME may also be advantageously used in combination with other active principles, selected from peripheral decarboxylase inhibitors, such as carbidopa or benserazide, or selective MAO-B inhibitors, such as Deprenyl (column 3, lines 4-12).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have combined safinamide, used to treat Parkinson's disease, as taught by Dostert, with a combination of L-dopa methyl ester and a peripheral decarboxylase inhibitor, as taught by Chiesi, for the same purpose. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose ....[T]he idea of combining them flows logically from their having been

individually taught in the prior art.', *In re Kerkhoven*, 626 F.2d 846, 850,205 USPQ 1069, 1072 (CCPA 1980).

Thus, in view of the foregoing art made of record, it would have been obvious to one in the art to have combined L-dopa (with or without decarboxylase inhibitor) with safinamide in the treatment of Parkinson's disease.

Claims 65 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dostert (US Patent No. 5,236,957) and Chiesi (US Patent No. 5,017,607) as applied to claims 57-64 and 67 above in further view of Chenard (US Patent No. 6,258,827 B1).

Dostert and Chiesi are discussed above.

Neither Dostert nor Chiesi teach the composition further comprising a catechol-*O*-methyltransferase inhibitor, such as tolcapone or entacapone.

Chenard teaches that there are classes of compounds reported as being useful in the treatment of Parkinson's disease namely, among others, D1, D2 agonists, monoamine oxidase-B inhibitors, levodopa and COMT inhibitors (column 12, lines 31-45), wherein COMT inhibitors include tolcapone and entacapone (column 13, lines 8-11).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have employed the combination of safinamide and levodopa for the treatment of Parkinson's as taught by Dostert and Chiesi and also administered

additional Parkinson's disease agents such as tolcapone or entacapone as taught by Chenard. Because such agents are well known in the art to treat the same disease, it would have been obvious to one in the art to have combined them. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose ....[T]he idea of combining them flows logically from their having been individually taught in the prior art.', *In re Kerkhoven*, 626 F.2d 846, 850,205 USPQ 1069, 1072 (CCPA 1980).

Conclusion

Claims 57-67 are not allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAHAR JAVANMARD whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/S. J./

Examiner, Art Unit 1627

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1627